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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/021,698	10/22/2001	Tim Keith	2976-4044US1	2256

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EXAMINER
SULLIVAN, DANIEL M

ART UNIT	PAPER NUMBER
1636	4

DATE MAILED: 04/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Application No.	Applicant(s)
10/021,698	KEITH ET AL.
Examiner	**Art Unit**
Daniel M Sullivan	1636

Office Action Summary

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-111* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-111* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-20, 31-36, 41-49, 56-59, 86-91 and 96-99, drawn to an isolated nucleic acid and variants thereof, and a vector, host cell, pharmaceutical composition, and kit comprising said nucleic acid, classified in class 536, subclass 23.5.

II. Claims 21-26, 37, 38, 50 and 51, drawn to an isolated polypeptide and a pharmaceutical composition and kit comprising said polypeptide, classified in class 530, subclass 350.

III. Claims 27-30, 39, 40, 52-55, 60 and 61, drawn to an antibody or fragment thereof and a pharmaceutical composition comprising said antibody, classified in class 530, subclass 387.1.

IV. Claims 62, 63, 66, 68 and 92-95, drawn to a method of diagnosis using the nucleic acid of Group I, classified in class 435, subclass 6.

V. Claims 64, 65 and 67, drawn to a method of diagnosis using the antibody of Group III, classified in class 435, subclass 7.1.

VI. Claims 69, 70, 73 and 74, drawn to a method of treatment comprising administering the nucleic acid of Group I, classified in class 514, subclass 44.

VII. Claims 71 and 72, drawn to a method of treatment comprising administering the host cell of Group I, classified in class 424, subclass 93.2.

VIII. Claims 75 and 76, drawn to a method of treatment comprising administering the polypeptide of Group II, classified in class 530, subclass 350.

IX. Claims 77 and 78, drawn to a method of treatment comprising administering the antibody of Group III, classified in class 530, subclass 387.1.

X. Claims 79-81, drawn to a transgenic mouse comprising a disruption in a gene comprising the nucleic acid of Group I and method of making said transgenic mouse, classified in class 800, subclass 8.

XI. Claim 83, drawn to a method of forming a crystal from the polypeptide of Group II, classified in class 530, subclass 350.

XII. Claims 100, 101, 104 and 105, drawn to a method of identifying a ligand using the polypeptide of Group II, classified in class 435, subclass 4.

XIII. Claims 102, 103, 106 and 107, drawn to a method of identifying a ligand using the nucleic acid of Group I, classified in class 435, subclass 6.

XIV. Claims 108 and 109, drawn to a method of treatment using a ligand identified by the method of Group XII, classified in class 424.

XV. Claims 110 and 111, drawn to a method of treatment comprising administering a compound identified by the method of Group XIII, classified in class 424.

The inventions are distinct, each from the other because of the following reasons:

The methods of Inventions IV to IX and XI to XV are unrelated, each to the other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

Inventions IV and V are directed to methods of diagnosis, Inventions VI-IX, XIV and XV are directed to methods of treatment, Invention XI is directed to a method of making protein crystals and Inventions XII and XIII are directed to methods of identifying a ligand. As each of these groups of methods are explicitly directed to achieving different outcomes, they clearly have different functions and effects. Furthermore, each group of methods comprises different modes of operation as evidenced by the distinct method steps set forth for each.

Each of the methods of diagnosis, methods of treatment and methods of identifying a ligand are distinct in that they are directed to methods which utilize patentably distinct products (see below). Therefore, the methods have different modes of operation and function dictated by the properties of the products used in the method.

The nucleic acids of Invention I are related to the protein of Invention II by virtue of encoding the same. The DNA molecule has utility for the recombinant production of the protein in host cells. Although the DNA molecule and protein are related since the DNA encodes the specifically claimed protein, they are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for processes other than the production of the protein, such as nucleic acid hybridization assay.

The nucleic acids of Invention I is related to the antibodies of Invention III by virtue of the antibodies' binding affinity for a protein encoded by the nucleic acid. Although the nucleic acids and antibodies are related via the polypeptide encoded by the nucleic acids, which binds to the antibodies and can be used to make the antibodies by immunization, they are distinct

inventions because they are physically and functionally distinct chemical entities, and the antibody can be made obtained by another and materially different process, such as by purification from a natural source or by immunization with chemically synthesized peptides. Further, the nucleic acid may be used for processes other than the production of the protein, such as a nucleic acid hybridization assay.

The polypeptides of Invention II are related to the antibodies of Invention III by virtue of binding affinity. Although the polypeptides and antibodies are related since the antibody binds to the polypeptide and can be raised by immunization with the polypeptide, they are distinct inventions because they are physically and functionally distinct chemical entities, and the antibody can be made obtained by another and materially different process, such as by purification from a natural source or by immunization with chemically synthesized peptides. Further, the polypeptide may be used for processes other than the production of the antibody, such as a standard in an assay for the presence of the protein.

The protein of Invention II and nucleic acid of Invention I are related to the transgenic animal of Invention X in that the animal can be produced using the nucleic acid of Invention I and comprises the protein of Invention II. The animal is distinct from the protein and nucleic acid, however, because they are physically and functionally distinct and the peptide and nucleic acid can be used for processes other than production of the transgenic animal, such as to raise antibodies, or screen for agents that bind to the protein or nucleic acid. Furthermore, patentability of the transgenic animal arises from the phenotypic characteristics of the animal; thus, patentability of the transgenic animal is not solely dependent upon the particulars of the nucleic acid or polypeptide comprised within the animal.

The antibodies of Invention III are unrelated to the transgenic animal of Invention X because they are physically and functionally distinct and the animal does not comprise the antibody of Invention III.

The nucleic acid of Invention I is unrelated to the methods of Inventions V, VIII, IX, XII, XIV and XV, which are directed to methods of using patentably distinct products. Likewise, the polypeptide of Invention II is unrelated to the methods of Inventions IV-VII, IX and XIII-XV, the antibody of Invention III is unrelated to the methods of Inventions IV, VI-VIII and X-XV, and the transgenic mouse of Invention X is unrelated to the methods of Inventions IV-IX and XI-XV.

The nucleic acids of Invention I are related to the methods of Inventions IV, VI, VII and XII as product and method of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid can be used in any of the patentably distinct methods of Inventions IV, VI, VII and XII (*Id.*). Likewise, the polypeptides of Invention II are distinct from the methods of using said polypeptides encompassed by each of the patentably distinct methods of Inventions VIII, XI and XII, and the antibodies of Invention III are distinct from the methods of using said antibodies encompassed by each of the patentably distinct methods of Inventions V and IX.

Each claim directed to a specifically disclosed sequence selected from the group consisting of SEQ ID NO:1-4687 is further restricted to a single sequence. Please note that this is not a species election. Each sequence is patentably distinct because they are unrelated sequences.

i.e. these sequences are unrelated because the protein encoded by these sequences differs in structure and in function and in biological activity. A restriction is applied to each Group. For an elected Group drawn to a nucleotide sequence, the Applicants must elect a single nucleic acid sequence "X", a single nucleic acid encoding a polypeptide "Y" and a single cDNA contained in clone "Z" (See MPEP 803.04).

The search of the selected sequence may include the complements of the selected sequences and, where appropriate, may include subsequences within the selected sequences (e.g., oligomeric probes and/or primers).

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. Similarly, proteins comprising unique amino acid sequences are structurally and functionally distinct. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequences are presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, or because each of the distinct Inventions comprise distinct elements and therefore cannot be searched coextensively, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 703-305-4448. The examiner can normally be reached on Monday through Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-9105 for regular communications and 703-746-9105 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

dms
April 17, 2003

JAMES KETTER
PRIMARY EXAMINER